

REMARKS

Status of the Claims

Claims 1, 5-30, and 35-68 are pending in this application. Claims 1, 27, 54-56, 61, and 68 are independent. Claims 66-68 have been added. Recitations in claims 66-68 are supported by the original disclosure, such as, for example, in Figs 1-10, and 16. Applicant respectfully submits that new claims 66-68 are allowable over the cited art.

In the Office Action, claim 9 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In addition, claims 11, 14, 21-23, and 36-41 were rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite. Also, claims 1, 5-11, 14-18, 27, 36-42, 47-52, 54-57, 59, 60, and 65 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith, III (U.S. Patent No. 6,491,928; hereinafter "Smith"). Further, claims 19-26, 28-30, 35, 45, 46, 53, and 58 were rejected under § 103(a) as being unpatentable over Smith in view of Kochinke (U.S. Patent No. 5,350,581; hereinafter "Kochinke"). In addition, claims 43 and 44 were rejected under § 103(a) as being unpatentable over Smith in view of Auguste et al. (U.S. Patent No. 6,338,839; hereinafter "Auguste"). Lastly, claims 12, 13, and 61-64 were rejected under § 103(a) as being unpatentable over Smith in view of Yoko (JP 04108710; hereinafter "Yoko").

Rejection Under 35 U.S.C. § 112, First Paragraph

With regard to the rejection of claim 9 under 35 U.S.C. § 112, first paragraph, although the Office Action alleges a lack of written description, the remarks in the Office Action appear to set forth an argument regarding enablement. For example, the Office Action alleges that

[t]he recitation of "freeze-dried substances" without any description of these substances and their correlation to the moisture absorbing compounds does not meet the written description requirement as one of ordinary skill in the art would not recognize or understand . . . what are the freeze dried materials that acts (sic) as moisture absorbing compounds.

Office Action at 3. The Office Action further alleges that

[t]he expression could encompass myriad of freeze-dried substances and applicants claimed "freeze-dried substances" represents (sic) only an invitation to experiment regarding possible means.

Id.

As explained in MPEP § 2163.04, "a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)." MPEP § 2163.04 further states that "[t]he examiner . . . must have a reasonable basis to challenge the adequacy of the written description" and that "[t]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Wertheim, 541 F.2d at 263, 191 USPQ at 97."

Applicant respectfully submits that there is no reasonable basis to challenge the adequacy of the written description and that no further clarification and/or examples are required for one of ordinary skill in the art to understand the scope of the term "freeze-dried substances" in the context of moisture absorbing compounds used in adhesive matrices. The Examiner has not demonstrated by a preponderance of evidence why a

person skilled in the art would not recognize the description of the invention defined by the claims. Accordingly, the § 112, first paragraph, rejection should be withdrawn.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Applicants respectfully traverse the rejection of claims 11, 14, 21-23, and 36-41 under 35 U.S.C. § 112, second paragraph. As stated in MPEP § 2173.02, “[t]he test for definiteness under 35 U.S.C. § 112, second paragraph, is whether ‘those skilled in the art would understand what is claimed when the claim is read in light of the specification.’

Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).” MPEP § 2173.02 further indicates that a claim is indefinite “[o]nly when a claim remains insolubly ambiguous without discernible meaning after all reasonable attempts at construction.” MPEP § 2173.02 clarifies that, with regard to the requirement of definiteness under 35 U.S.C. § 112, second paragraph, “[t]he essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity.

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.”

In addition, as clearly set forth in MPEP § 2173.04, “[b]readth of a claim is not to be equated with indefiniteness. MPEP § 2173.04 continues, “[i]f the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. § 112, second paragraph.”

A claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004) (holding that the disputed claim term ‘surrender value protected investment credits’ which was not defined or used in the specification was discernible and hence not indefinite because “the components of the term have well recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence”).

MPEP § 2173.02. (Emphasis added).

With regard to claim 11, the Office Action appears to object to a purported lack of further description and/or examples in the specification to explain various recitations of claim 11, such as “wetting agents,” “healing agents,” “freshener,” etc. Office Action at 4. However, there is no ambiguity as to the meaning of these terms as recited in claim 11. Accordingly, Applicant respectfully submits that no further explanation of the terms in claim 11 is required because these terms have well recognized meanings, and thus, one of ordinary skill in the art would readily understand the scope of these terms as used in claim 11. Moreover, the mere breadth of these claim terms does not render claim 11 indefinite.

Claim 11 was also rejected because the claim seems to have been construed to purportedly include several instances of a range within a range, as well as several recitations of purportedly overlapping ranges. Office Action at 4. Claim 11 recites a listing of active agents without causing any ambiguity or reciting a range within a range. Moreover, even if some of the listed items might be related, such relationships do not render the scope of the claim as indefinite. Applicants respectfully submit that claim 11 sets out and circumscribes particular subject matter with a reasonable degree of clarity.

and particularity and that, accordingly, the rejection of claim 11 under § 112, second paragraph, should be withdrawn.

Claim 14 was rejected because the recitation of “vinyl” allegedly does not “set forth the metes and bounds of the claim.” Office Action at 5. Again, the Office Action apparently objects to the purported lack of further description and/or examples of applicable vinyl compounds. However, no further explanation is needed for one of ordinary skill in the art to understand the scope of claim 14. There is no ambiguity as to the meaning and scope of the term “vinyl” in the context of adhesive matrices. Claim 14 specifies that “the adhesive matrix comprises a[n] . . . adhesive comprising one of vinyl, PVA, PVP . . . ” (Emphasis added). Applicant respectfully submits that one of ordinary skill in the art would readily understand the scope of “vinyl” as a component of an adhesive matrix.

Claim 14 was also rejected because it recites “wherein the adhesive matrix comprises a permanent adhesive comprising one of vinyl, PVA, PVP . . . ,” while the specification, at page 8, lines 22-23, appears to refer to PVA and PVP as “revisable” adhesives. Office Action at 5. Contrary to the Office Action’s apparent assertion, PVA and PVP are disclosed as being components of both revisable adhesives and permanent adhesives. Therefore, the language of claim 14 is technically accurate, as is the language at page 8, lines 22-23 of the specification.

Applicant has amended the specification to include language consistent with that of claim 14. More specifically, the paragraph beginning on page 8, line 22 has been amended to read “The adhesive matrix 11 may be a permanent adhesive including vinyl, PVA, PVP, pseudo-latex, an acrylic polymer, a polyurethane, or a latex

elastomer." Applicant respectfully submits that this amendment to the specification eliminates any purported inconsistency between claim 14 and the specification. Furthermore, the amendment to the specification is supported by original claim 14, which was part of the originally filed disclosure.

Claims 21-23 were rejected for allegedly lacking antecedent basis for the recitation of "support layers." Office Action at 5. However, the only place the term "support layers" appears in claims 21-23 is in claim 22, which refers to "the first and third support layers" in line 5 of the claim. Contrary to the allegation in the Office Action, claim 22 provides proper antecedent basis for the recitation of "the first and third support layers" by reciting earlier in the claim "a first support layer" and "a third support layer" in lines 2 and 4 respectively. Further, since the phrase "support layers" does not appear in either claim 21 or 23, and since neither claim 21 nor claim 23 depends from claim 22, there is no basis for the rejection of these claims under § 112, second paragraph. Accordingly, the § 112, second paragraph, rejection of claims 21-23 should be withdrawn.

Claims 36-41 were rejected under § 112, second paragraph, because the expressions "additional active agent configured to swell," "additional active agent soluble in the solvent," and "compound configured to swell," are allegedly not defined in the specification. Office Action at 5. As an initial matter, claim 41 does not contain any of these expressions and is not dependent on any of claims 36-40, and thus, there is no basis for this rejection of claim 41 under § 112, second paragraph. In addition, the discussion of an "additional active agent" is found in the specification at, for example, page 14, lines 22-32, which explains that, in some embodiments, the adhesive matrix

may include more than one active agent. Applicant respectfully submits that the use of active agents configured to swell in order to facilitate their release from a substrate would be understood by those having ordinary skill in the art. In addition, Applicant respectfully submits that the solubility of the active agent in a solvent is explained sufficiently in the specification, such that no further explanation is necessary to clarify what is meant by "additional active agent soluble in the solvent." See, e.g., page 1, line 25--page 2, line 22.

Rejections Under 35 U.S.C. § 103(a)

The rejection of claims 1, 5-11, 14-18, 27, 36-42, 47-52, 54-57, 59, 60, and 65 under § 103(a), based on Smith, fails to establish a prima facie case of obviousness for at least the reason that Smith does not disclose or suggest all the recitations of independent claims 1, 27, 54-56, and 61. For example, Smith fails to disclose a composite structure including, among other things, "at least one adhesive matrix," as recited in each of independent claims 1, 54-56, and 61. Smith also fails to disclose a method of manufacturing a composite structure including, among other things, "coating a first non-adhesive layer with an adhesive matrix," as recited in independent claim 27.

The pending Office Action alleges that Smith discloses a "therapeutic agent comprised within composition comprising adhesive material." Pending Office Action at 6. This allegation is inconsistent with the Office Action mailed May 19, 2004, which admitted that "Smith does not expressly teach that the cleansing composition is in the form of an adhesive matrix." May 19, 2004 Office Action at 3. Applicant respectfully submits that the May 19, 2004 Office Action was correct in its assessment that Smith does not teach an "adhesive matrix," as recited in independent claims 1, 54-56, and 61, because the portion of Smith cited in the pending Office Action as allegedly disclosing

an adhesive matrix (col. 31, lines 21-25) does not disclose adhesive at all, but rather a “coacervate forming composition,” which is merely a material tending to form clusters/droplets. Smith lacks any disclosure of the “coacervate foaming composition” being an adhesive.

For at least the foregoing reasons, Applicant respectfully submits that Smith fails to disclose or suggest each and every element of the claims. Therefore, at least one essential criteria for establishing a prima facie case of obviousness is lacking and, accordingly, the § 103(a) rejection of claims 1, 5-11, 14-18, 27, 36-42, 47-52, 54-57, 59, 60, and 65 is should be withdrawn.

In addition, the Examiner admits, in the pending Office Action, that Smith fails to teach that “the two non-adhesive substrates are bonded permanently by the middle layer.” Office Action at 7; emphasis added. The Examiner alleges, however, that Smith discloses that “the [alleged] adhesive used by [Smith] in the middle layer comprises acrylic polymer and polyurethane that are claimed by Applicant as permanent adhesive in claim 14 (col. 32, lines 40-43; col. 37, lines [sic] col. 39, lines 16-17).” Office Action at 7. From this alleged disclosure in Smith, the Examiner concludes that “the middle layer disclosed by [Smith] that [allegedly] comprises adhesive including acrylic acid polymer or polyurethane polymers is expected to be able to permanently bond to the first and second non-adhesive substrates.” Id. That is, the pending Office Action attempts to remedy Smith’s acknowledged failure to disclose an “adhesive matrix” by alleging that components of the purported adhesive material in Smith are claimed by Applicant as permanent adhesive. However, the Office Action does not point to any suggestion, motivation, or teaching to modify the alleged adhesive in Smith into a

permanent adhesive. Moreover, contrary to the allegations in the Office Action, the present application does NOT disclose that the materials in claim 14 (i.e., acrylic polymer and polyurethane) are necessarily permanent adhesives. Rather, the present application discloses a permanent adhesive which can include acrylic polymer and polyurethane as components of the permanent adhesive.

Acrylic and polyurethane are broad categories of polymers, which include many different materials that have many varied uses. Adhesive materials are only one of many known forms of such materials. Accordingly, the simple fact that Smith might mention acrylic and polyurethane does not provide any suggestion, motivation, or teaching to modify these materials to be a permanent adhesive. Therefore, another essential criteria for establishing a *prima facie* case of obviousness is lacking. For at least the foregoing reasons, the § 103(a) rejection of claims 1, 5-11, 14-18, 27, 36-42, 47-52, 54-57, 59, 60, and 65 should be withdrawn.

With regard to the § 103(a) rejection of claims 19-26, 28-30, 35, 45, 46, 53, and 58 as being unpatentable over Smith in view of Kochinke, the Office Action acknowledges that Smith "does not teach more than one superimposed layers [sic] containing adhesive or pile of the article." Office Action at 8. In an attempt to cure this acknowledged deficiency of Smith, the Office Action relies Kochinke solely for an alleged disclosure of a multilayer device having "more than one therapeutic agent contained in different adhesive matrices" (*Id.*). Kochinke does not cure the deficiencies of Smith noted above with regard to independent claims 1, 27, and 56, from which claims 19-26, 28-30, 35, 45, 46, 53, and 58 respectively depend. For at least this

reason, the § 103(a) rejection of claims 19-26, 28-30, 35, 45, 46, 53, and 58 should be withdrawn.

With regard to the § 103(a) rejection of claims 43 and 44 as being unpatentable over Smith in view of Auguste, the Office Action acknowledges that Smith “does not teach the polyamide in the powder form.” Office Action at 9. The Office Action relies on Auguste for the sole purpose of attempting to cure this acknowledged deficiency of Smith. Auguste does not cure the above-noted deficiencies of Smith with regard to independent claim 1, from which claims 43 and 44 ultimately depend. For at least this reason, the § 103(a) rejection of claims 43 and 44 should be withdrawn.

With regard to the § 103(a) rejection of claims 12, 13, and 61-64 as being unpatentable over Smith in view of Yoko (JP 04108710; hereinafter “Yoko”), the Office Action acknowledges that Smith “does not teach magnetizable particles in the therapeutic composition.” Office Action at 10. The Office Action relies on Yoko for the sole purpose of attempting to cure this acknowledged deficiency of Smith. Yoko does not cure the above-noted deficiencies of Smith with regard to independent claim 1, from which claims 12 and 13 ultimately depend, nor does it cure the above noted deficiencies of Smith with regard to independent claim 61 above. For at least these reasons, the § 103(a) rejection of claims 12, 13, and 61-64 should be withdrawn.

Conclusion

For at least the foregoing reasons, Applicant respectfully submits that each of independent claims 1, 27, 54-56, 61, and 68 is allowable. Each of claims 5-26, 30, 35-53, 57-60, and 62-67 ultimately depends from one of these allowable independent claims and, therefore, should be allowable for at least the same reasons that the

respective claim from which it depends is allowable. Additionally, these dependent claims include further limitations that distinguish from the cited art.

The Office Action contains a number of statements reflecting assertions and/or allegations concerning the claims and/or cited art. Regardless of whether any such statement is identified above, Applicant declines to subscribe to any assertion or allegation in the Office Action.

In view of the above, Applicant respectfully requests that the rejections be withdrawn and that the application be allowed. Please grant any additional extensions of time required to enter this response and charge any required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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